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TITLE: A Translational Approach to Validate in Vivo Anti-tumor Effects of Chloroquine on Breast Cancer Risk

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INTRODUCTION

SUBJECT & PURPOSE: This translational epidemiologic study aims to confirm preclinical data on the chemopreventive potential of chloroquine (aminoquinoline), a well-characterized anti-malarial drug. **BACKGROUND:** Exposure to chloroquine, an off-patent anti-malarial drug with a 60-year history of use by millions, reduces the incidence of breast cancer in genetically programmed rats by 37%. **METHODS & SCOPE:** About 65% of Peace Corps volunteers received chloroquine prophylactically between 1965 and 1990. Therefore, we will collect chloroquine exposure, breast cancer risk, and breast cancer diagnosis data from returned volunteers who served during this period through an online application. We will characterize participants into chloroquine exposed and unexposed groups, based on country of service and self-reported exposure status. The cost and time efficiencies afforded by this study design will allow the translation of preclinical data on breast cancer chemoprevention into public health and potentially promote the repositioning of a well-characterized and inexpensive drug.

BODY

The following is an update on tasks outlined in the proposed Statement of Work.

Task 1. Obtain human subjects regulatory approval of study (months 1-4)

The human subjects regulatory approval is complete for the study. Baylor College of Medicine's IRB (Appendix A) and Human Research Protection Office (HRPO) Office of Research Protections (ORP) U.S. Army Medical Research and Materiel Command (USAMRMC) have approved the human subjects application.

Task 2. Create a breast cancer survey instrument (month 1-5)

Participant workflow documents have been developed (Appendix B), and a questionnaire has been written (Appendix C). The application to collect the data using a web-based participant interface has been developed and is in the process of testing the functional elements of the system.

Dr. Queen at the University of Houston (UH) contributed to the design of the questionnaire instrument in year 1. She has left the University of Houston and will not be involved in the study in year two. The subaward to UH will not be needed in year 2 of the study. The year 2 funding budgeted for the UH subaward will be used at BCM for application development of CorpsChronicles.

Task 3. Data Management System (months 1-18)

No existing system of which we are aware has all of the technical features this project requires, nor the ability to meet its statistical sampling needs. During year 1 of funding, we finalized technical documents, architected the data model for the database, and developed CorpsChronicles, a secure, database-backed web application developed to manage large, socially oriented epidemiologic studies. CorpsChronicles will be used to collect information from RPCVs to determine if chloroquine exposure in this cohort associates with reduced breast cancer incidence compared with the general US population.

CorpsChronicles was designed to (i) allow research subjects to securely answer dynamic questionnaires; (ii) manage electronic recruitment and referral workflows; (iii) send email reminders to participants to complete surveys; and (iv) provide feedback to end users on the overall progress of the study in a way that does not compromise the results. Because breast cancer known risk factors include family history, race, and lifestyle, the online survey elicits self-reported data on potential confounding variables which

will be accounted for in the statistical analysis to maximize internal validity. Two hundred highly connected RPCVs were selected as initial seeds, with a goal of up to 18,000 respondents across all chains. Interim analyses will be performed at one and two months post-activation to ensure appropriate accruals with the sampling method, Respondent Driven Sampling (RDS).

Because CorpsChronicles is a complex system that must support myriad workflows, be easy-to-use by a diverse body of respondents, be able to accommodate hundreds of simultaneous end users, and support usage outside of the primary intended workflows, we elected to be as cautious as possible in designing and testing the system, which was released for internal testing in late May 2013. This choice was made because i) any major issues not caught in the planning and testing phases may cause end users to not complete their surveys, ii) these same issues would likely reduce the number of respondents making the study fall potentially short of its target accrual and iii) we anticipate that accruals will be extremely rapid owing to the high level of enthusiasm from RPCVs for the project.

We do not expect that delaying roll-out in favor of creating a robust system will impact the time to complete the study. As part of our planning process, we created myriad software architecture, object model, workflow and data diagrams and other diagrammatic documentation to ensure that we followed industry standard best-practices, which are often set aside in academic software development. For testing purposes, we designed a multi-phased procedure in which we tested the system with BCM employees (including FTE from staff not covered by this award) under a variety of scenarios to ensure that the system functioned as intended. After CorpsChronicles passes this initial internal testing, it will be tested by an internal group of women from the public; these women have differing levels of familiarity with websites and, most importantly, no prior knowledge of how the system should function thus making them excellent real-world test cases. During year 2 of the study, the application developer will continue to develop iterative revisions of the system to refine existing features, add new features and address issues that arise through production use.

Task 4. Recruit a cohort of 14,000 to 18,000 female returned Peace Corps volunteers who served from 1961 through 1990 in both malaria-endemic and non-endemic parts of the world and data collection (months 3-18)

We created a database of eligible potential volunteers who have expressed interest in participating in BCM research from a previously IRB approved study “CREATING A DATABASE OF POTENTIAL PARTICIPANTS,” in which RPCVs were recruited at the Peace Corps 50th Anniversary conference in Washington DC in September 2012. This database will serve as the source of “seeds” to begin Respondent Driven Sampling.

We expect to begin data collection by emailing all potential volunteers in the database an invitation to participate in the study with link to online survey instrument with an embedded number to identify each responder beginning in early fall 2013, or as soon as all the internal testing of the application is complete.

We have worked with National Peace Corps Association (NPCA) to draft informational text about the study that would be acceptable to Returned Peace Corps Volunteers (Appendix D). We are working with NPCA so that when the online questionnaire launches, we will publish information and a link to the study’s public informational website on widely visited RPCV online communities, including: websites and blogs, including PeaceCorpsConnect.org, PeaceCorpsWorldwide.org, and the websites of independent and NPCA-affiliated RPCV member groups, NPCA’s monthly e-newsletter with 35,008 subscribers, mass emails or listserv posts to membership of NPCA, Peace Corps Worldwide, and independent and NPCA-affiliated RPCV member groups, and social media tools including Facebook, Twitter, LinkedIn, and Ning.

The large sample size will be obtained using respondent-driven sampling of social networks methodology, we will request 3 referrals from each respondent for other eligible RPCVs, and track and analyze the referral chain using unique identifiers.

Task 5. Identify the cause of death of deceased female returned Peace Corps volunteers who served from 1961 through 1990 (months 6-18)

In the original protocol and grant applications, we proposed using the National Death Index (NDI) to match the names of the deceased provided by study participants to those in the NDI to verify causes of death. However, it was determined that relying on participants to provide accurate identifying information on those potential participants who have died would yield an unrepresentative sample of those who died and may be upsetting to participants. Therefore, Network Scale-Up Method (NSUM) will be used to estimate the number of deceased RPCVs, eliminating both the need to ask for identifying information of those who have died from participants and the use of the National Death Index.

NSUM estimates the size of a hidden or hard-to-reach population (i.e., deceased RPCVs) by assuming that, in general, people's social networks are representative of the general population in which we live and move (HR Bernard, 2010). Using the questions already crafted for our primary sampling mechanism of RDS, we will ask the respondents one additional question to determine the number of female RPCVs they know who have died. This number, along with the number of female RPCVs each respondent knew and the total number of female Peace Corps Volunteers who served between 1961 and 1990, will be used to estimate the number of deceased women. Implementation of NSUM eliminates the need for NDI, and thus we request that the funds intended for NDI be re-distributed.

Task 6. Examine the association between chloroquine exposure and breast cancer in our cohort of RPCVs who served between 1961 and 1990 (months 18-21)

Task 6 will begin in Year 2 of the study.

Task 7. Disseminate findings (months 21-24)

We have presented posters on this project at two conferences and have submitted an abstract for consideration at one conference. See Reportable Outcomes section for references and Appendices for posters and manuscripts.

KEY RESEARCH ACCOMPLISHMENTS

- CorpsChronicles:** Development of a Java Enterprise Edition 6 application that uses the model-view-controller architecture with the JBoss Seam framework to manage its various components. The application runs within JBoss 7 middleware and utilizes Oracle 11g for data persistence, though Hibernate makes it possible to swap out Oracle for other database management systems. Security is managed by enhanced Seam security, encrypted passwords, role-based permissions, Captchas, and unique "coupon" codes that serve as keys for respondents. Referrals of respondents are based on a novel social network sampling methodology, Respondent-Driven Sampling (RDS), in which initial respondents ("seeds") identify members of their social network who may want to participate and these members in turn identify members of their network thus creating network "chains" for each seed. Data from links in each chain are compared back to their seed data using RDSAT freeware; demographic and clinical characteristic data is compared between groups using chi-square or Fisher's exact test and t-test or Wilcoxon rank-sums. Multivariate logistic regression is used to assess associations between chloroquine exposure and breast cancer incidence, with the Network Scale-Up Method, a social networking method, applied to estimate the hard-to-count population of RPCVs.

REPORTABLE OUTCOMES

Publications:

Mayfield P, McOwiti A, Barney J, Qu Shijing, Sexton KR, Harris AM, McArthur K, Hilsenbeck SG, Bondy ML, Conneely O, Spitz M, Dacso CC, Becnel LB. CorpsChronicles: An Application Leveraging Social Networks for Online Epidemiologic Survey Studies. Submitted to American Medical Informatics Annual Symposium Washington, DC. November 16-20, 2013. (Appendix E)

Sexton K, Harris AM, McArthur K, Bondy M, Hilsenbeck S, Becnel L, Mayfield P, Conneely O, Spitz M, Queen C, Dacso C. Designing a translational epidemiologic study: Chloroquine and breast cancer chemoprevention in Returned Peace Corps Volunteers. 140th APHA Annual Meeting, San Francisco, CA. October 2012. (Appendix F)

Mayfield, PK, McOwiti, AM, Barney, J, Darlington, Y, Vanjani, G, and LB Becnel. C3PR, CODR & Corps Chronicles: Case Studies of Clinical and Epidemiological Research Databases within the DLDCC. Dan L. Duncan Cancer Center 2012 Symposium. Baylor College of Medicine. Houston, TX. (Appendix G)

Experience/training supported by this award: One undergraduate student, Adesola Oyewole, University of Houston, received summer training in clinical research, June – August 2012.

CONCLUSION

At this point in the study, before data collection begins, we do not yet have results to report.

REFERENCES

Bernard HR, Hallett T, Iovita A, et al. Counting hard-to-count populations: the network scale-up method for public health. Sex Trans Inf. 86(Suppl 2): ii11-ii15, 2010.

APPENDICES

- A. Baylor College of Medicine IRB approval
- B. Participant Workflow documents
- C. Questionnaire used in CorpsChronicles
- D. Study Description developed with NPCA
- E. Mayfield P, McOwiti A, Barney J, Qu Shijing, Sexton KR, Harris AM, McArthur K, Hilsenbeck SG, Bondy ML, Conneely O, Spitz M, Dacso CC, Becnel LB. CorpsChronicles: An Application Leveraging Social Networks for Online Epidemiologic Survey Studies. Submitted to American Medical Informatics Annual Symposium Washington, DC. November 16-20, 2013.
- F. Sexton K, Harris AM, McArthur K, Bondy M, Hilsenbeck S, Becnel L, Mayfield P, Conneely O, Spitz M, Queen C, Dacso C. Designing a translational epidemiologic study: Chloroquine and breast cancer chemoprevention in Returned Peace Corps Volunteers. 140th APHA Annual Meeting, San Francisco, CA. October 2012.
- G. Mayfield, PK, McOwiti, AM, Barney, J, Darlington, Y, Vanjani, G, and LB Becnel. C3PR, CODR & Corps Chronicles: Case Studies of Clinical and Epidemiological Research Databases within the DLDCC. Dan L. Duncan Cancer Center 2012 Symposium. Baylor College of Medicine. Houston, TX.

March 13, 2013



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H-31160 - A TRANSLATIONAL APPROACH TO VALIDATE IN-VIVO ANTI-TUMOR EFFECTS OF CHLOROQUINE ON BREAST CANCER RISK

APPROVAL VALID FROM 1/23/2013 TO 7/2/2013

Dear Dr. DACSO

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

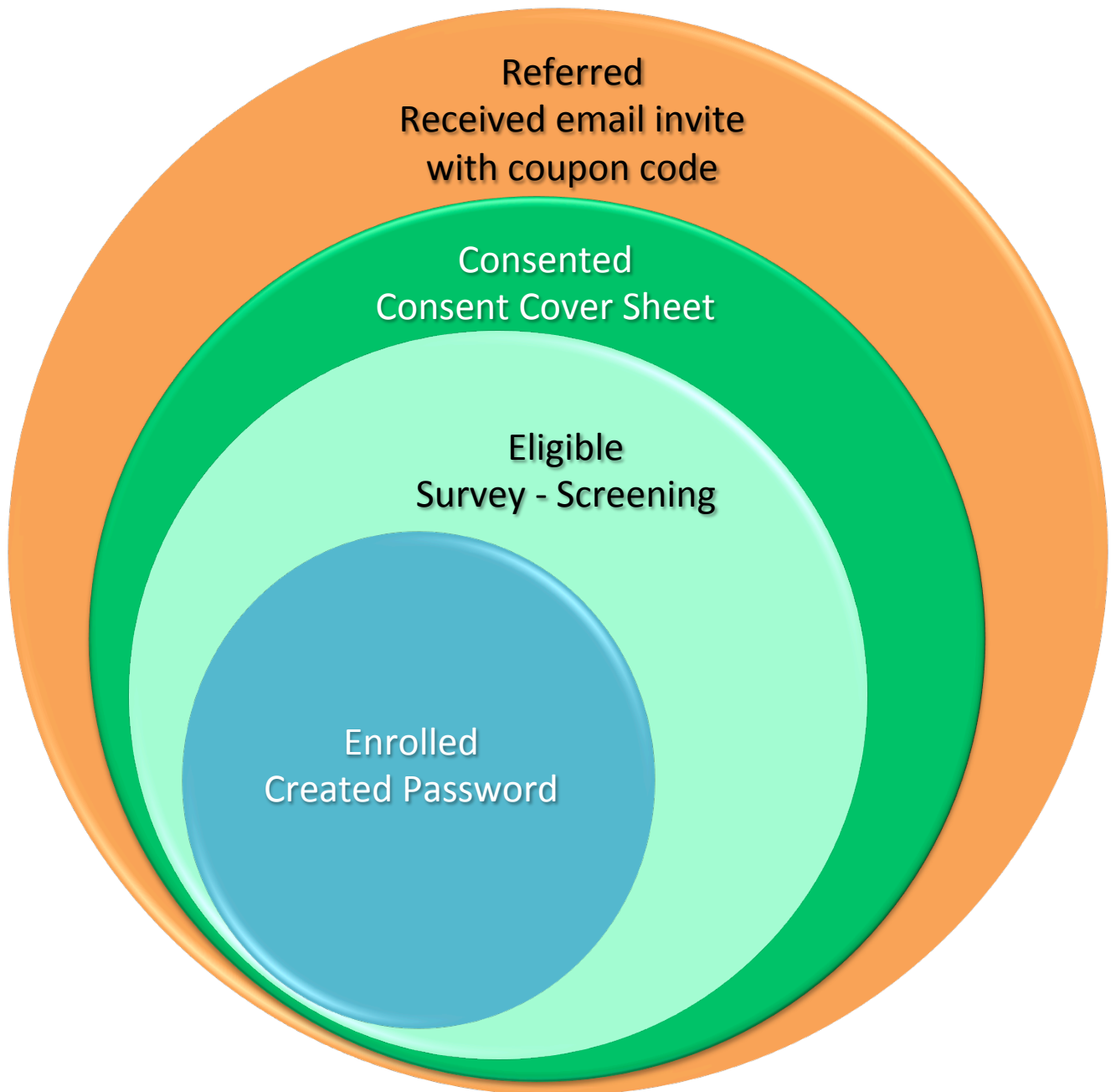
A handwritten signature in cursive script, reading "Danielle R. Sorelle".

DANIELLE R SORELLE,
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals



PARTICIPANT WORKFLOW DOCUMENT

Enrollment Process

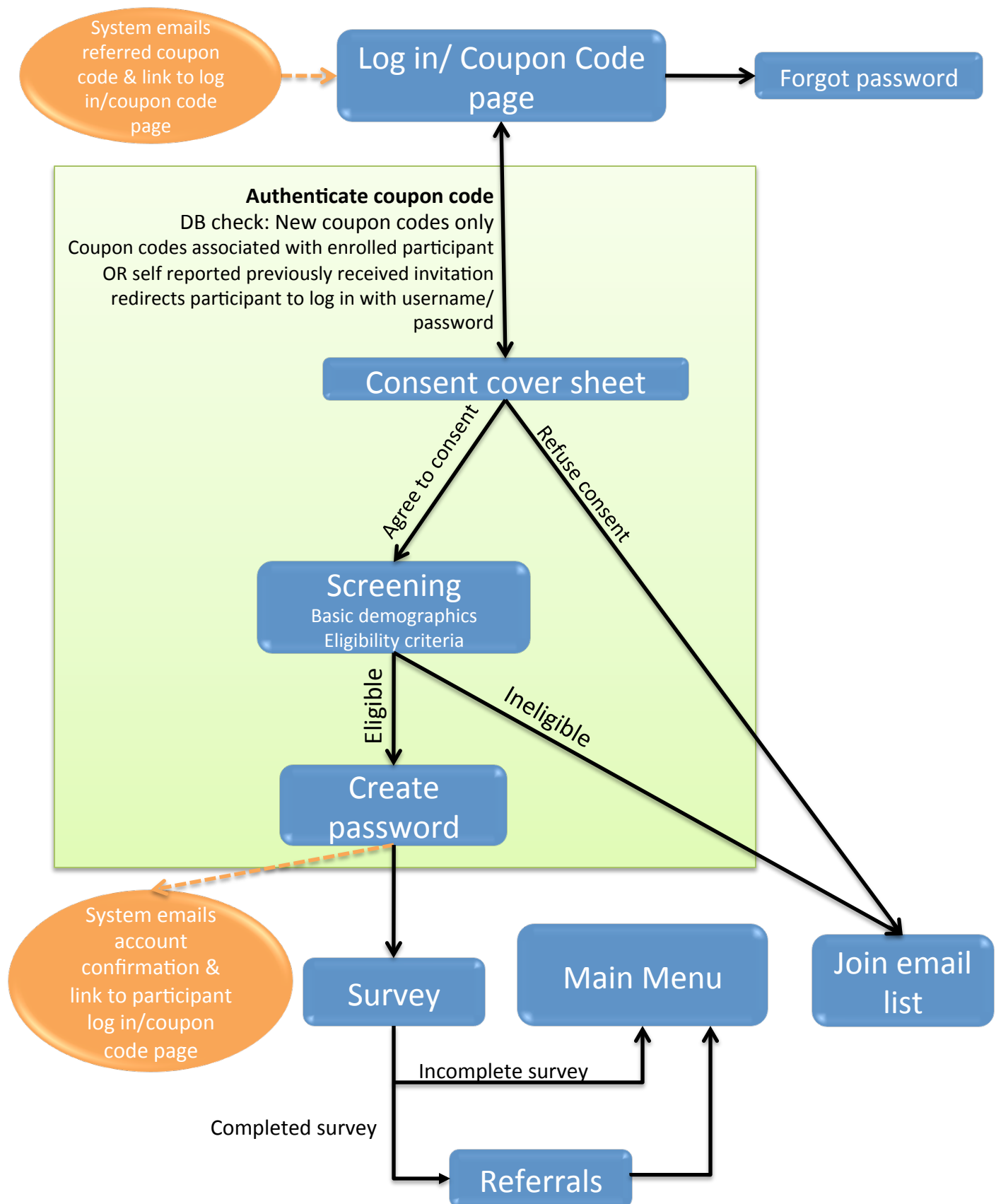


PARTICIPANT WORKFLOW DOCUMENT

Public Website Workflow

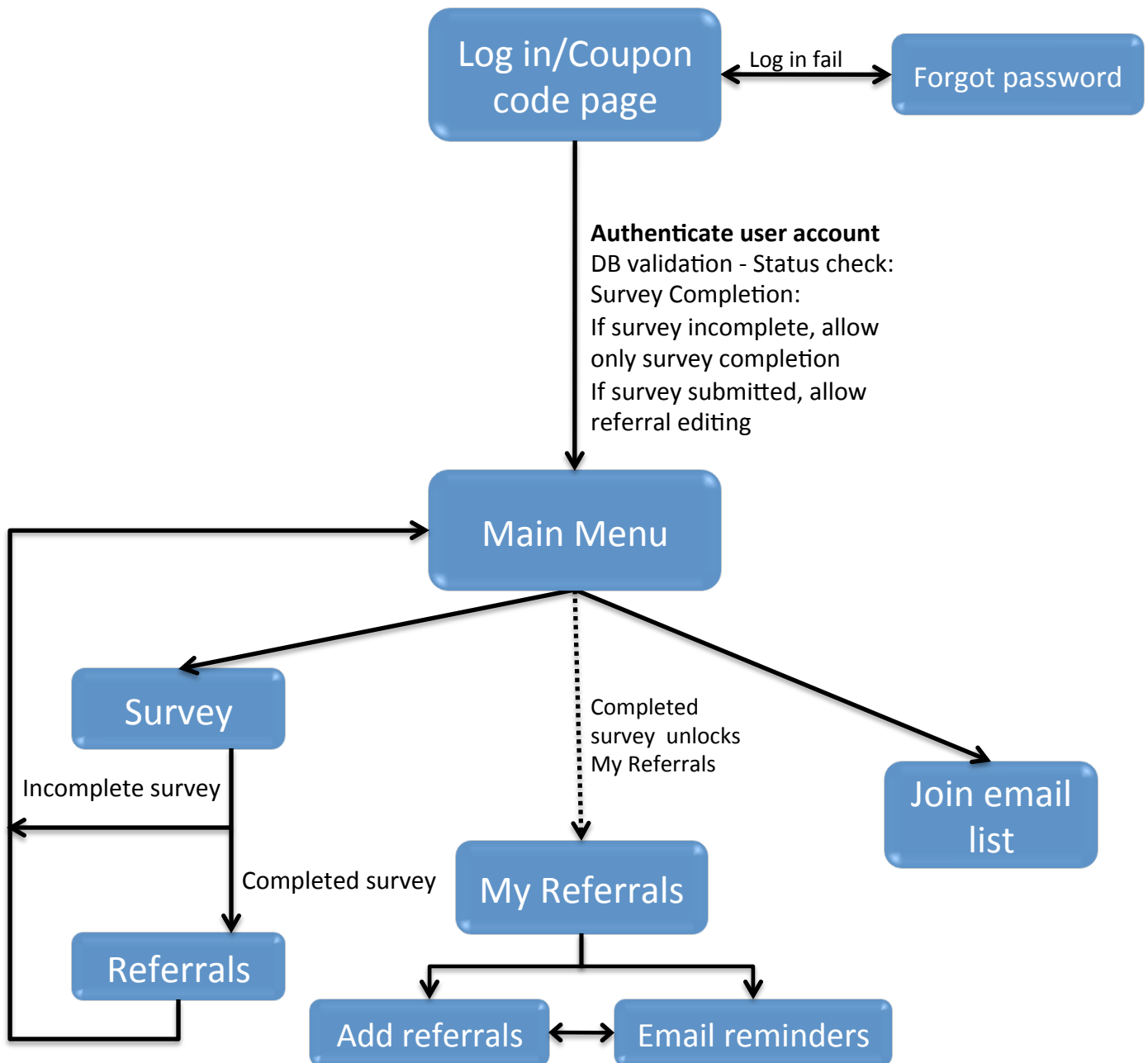


New Referral Workflow




PARTICIPANT WORKFLOW DOCUMENT

Returning Participants Workflow



PARTICIPANT WORKFLOW DOCUMENT

Sample Screen: Log in/Coupon Code page

Project Name

BCM Logo

Need help? Contact the study team.
Telephone: (713) XXX-XXXX
Email: XXXXXX@bcm.edu

Log In

Did you receive an email invitation to participate in the study?
Please copy and paste the coupon code in your email into the box below to enter the study site.

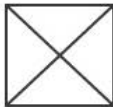
Returning participant?

Welcome back! Please log in.

Email:

Password:

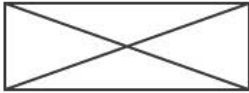
[Forgot password?](#)


NPCA LOGO


This is a password protected site for enrolled participants of the study titled A Translational Approach. . . For information about the study please visit the public study website at www.XXXXXX.edu.


PARTICIPANT WORKFLOW DOCUMENT

Sample Screen: Main Menu



Project Name
Sub-Project name



[Log out](#)

Need help? Contact the study team.
Telephone: (713) XXX-XXXX
Email: XXXXXX@bcm.edu

Main Menu

[My survey](#)[My referrals](#)[About us](#)[My account](#)[Contact us](#)

Thank you for completing the survey
<Message here will be based on DB validation status check. Other headline options: Please complete your survey/Welcome back>
You may log into this website anytime using your email address and the password to view the status of your referrals and add new referrals. Also, you can see how close we are to reaching our goal of reaching 18,000 RPCVs.

My Action Items

Survey: 70% Complete

Referrals: 70% Complete

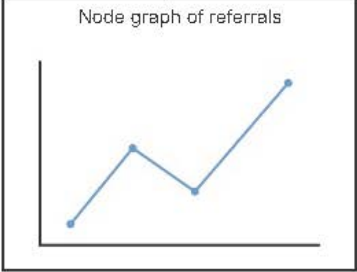
Complete Survey

Update or email your referrals

Study Recruiting Status 70% Complete

Your Peace Corps Volunteer Network

Node graph of referrals

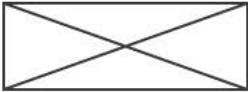


[Partner of the National Peace Corps Association](#)
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PARTICIPANT WORKFLOW DOCUMENT

Sample Screen: Survey



Project Name
Sub-Project name



 [Log out](#)

Need help? Contact the study team.
Telephone: (713) XXX-XXXX
Email: XXXXXX@bcm.edu

Breast Health History

Have you ever had a mammogram?

☐ Yes
☐ No
☐ Unknown / refuse to answer

When was your last mammogram?

Month

Year

Have you ever had a breast biopsy?

☐ Yes
☐ No
☐ Unknown / refuse to answer

How many breast biopsies (positive or negative) have you had?

3

Have you ever had at least one breast biopsy with atypical hyperplasia?

☐ Yes
☐ No
☐ Unknown or refuse to answer

Have you ever been diagnosed with breast cancer?

☐ Yes
☐ No
☐ Unknown or refuse to answer

Back

Save

Save & Next

PARTICIPANT WORKFLOW DOCUMENT

Email Notifications

Study Site

1. Invitation to Participate (Seeds and Referrals)
2. Account Creation Confirmation (Seeds and Referrals)
3. Reminder to Start Survey (Seeds and Referrals)
4. Reminder to Complete Survey (Seeds and Referrals)
5. Reminder to Start Referrals (Seeds and Referrals)
6. Reminder to Complete Referrals (Seeds and Referrals)

Public Site

1. Mailing List Confirmation

Questionnaire used in CorpsChronicles

About You <Screening>

1. Name* _____
FIRST MIDDLE LAST
2. Email address* _____
3. Confirm email address* _____
4. May we contact you if we have further questions about your responses?
☐ Yes ☐ No
5. Date of Birth* ____ / ____ / ____
MM DD YYYY
6. Place of birth City _____ State _____
or
☐ Check box if not born in the United States
If foreign-born, list country of birth: _____
7. Race (Check all that you MOST CLOSELY identify):
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African-American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Unknown or refuse to answer
8. Ethnicity (Check one that you MOST CLOSELY identify):
☐ Hispanic or Latino
☐ Not Hispanic or Latino
☐ Unknown or refuse to answer
9. Sex*
☐ Male
☐ Female

Your Peace Corps Service

10. Country of Service <drop down list of all PC countries>*

Month / Years of Service: _<drop down Jan – Dec>_ / __<dropdown list 1961-2015>_ -
__<drop down Jan – Dec>_ / ____<dropdown list 1961-2015>____

*Require response on years of service (Month of service not required.)

BUTTON: Add another country/ year of service

*Repeat these questions as many times as the RPCV has tours of service.

Are you currently active duty military personnel?*

- ☐ Yes
- ☐ No

Create Password

Please create a password for this survey. With your email address and password, you will be able to log into this website to finish your incomplete survey, add RPCV referrals and see the status of previously submitted referrals, and view study updates.

Your username is the email address at which you received your emailed survey invitation. Please create a password below.

Password

Confirm password

Your RPCV Social Network

The following questions are about your fellow volunteers in the Peace Corps. For the purposes of this study, the definition of knowing someone is that you know them and they know you by sight or by name and that you could contact them.

11. Approximately how many women do you know who served in the Peace Corps at any time between 1961 and 1990?

_____ women

12. Of those women you know/knew in the Peace Corps during that time period, about how many of them served at the same time and same country you served?

_____ women

13. Of those women you know/knew in the Peace Corps during that time period, about how many of them did you meet after you returned home?

_____ women

14. Of those women you know/knew in the Peace Corps during that time period, about how many of them have died since you've returned home?

_____ women

Your History of Medications to Treat or Prevent Malaria

Chloroquine is a drug that is taken to prevent or treat malaria. When it is taken to prevent malaria it is taken once a week. Other names for chloroquine are: Chloroquine phosphate oral and Aralen phosphate. Malarone, Lariam, Paludrine, and Doxycycline are other drugs that are sometimes used for malaria prevention. They are not the same as Chloroquine.

15. Have you ever taken a drug to prevent or treat malaria at any time in your life?

- ☐ Yes
☐ No
☐ Unknown

If yes, please complete the box below beginning with any medications taken to prevent or treat malaria during your Peace Corps service. You can add as many drugs into the table as needed.

Drug Name	Peace Corps Use?	Country where Taken	Reason	Approximate Time Taken	How Often Drug was Taken
Drop Down (include Do Not Know and Other)	Y/N	Drop Down (Include Do Not Know and Other)	Prevention Treatment	Mm/yy-mm/yy	Daily Weekly Bi-Weekly Other

BUTTON: ADD A DRUG

Did you take a drug that is not in this list? Please contact the study coordinator at XXX-XXX-XXXX.

16. Have you ever taken chloroquine for another reason?

- ☐ Yes
☐ No **Skip to Question 18.**
☐ Unknown **Skip to Question 18.**

17. If you took chloroquine for another reason, please complete the following:

Reason for Use: _____

Approximate Time Taken:
<dropdowns for MM> <Dropdowns for YYYY> - <dropdowns for MM> <Dropdowns for YYYY> Menstrual History

The next set of questions is about your menstrual periods.

18. How old were you when you started your first menstrual period?

_____ years

19. Have you reached menopause, that is your periods have stopped for 12 months or longer for reasons other than pregnancy, or you have no uterus?

☐ Yes

☐ No, but periods are irregular **Skip to Question 22.**

☐ No **Skip to Question 22.**

☐ Refuse to Answer **Skip to Question 22**

20. How old were you when your periods stopped?

_____ years or ☐ Check box if you do not know or refuse to answer

21. Why did your periods stop?

☐ Natural menopause

☐ Surgical menopause

☐ Chemotherapy or radiation treatment

☐ Do not know

☐ Other _____

Pregnancy History

22. Have you ever been pregnant? Please include live births, stillbirths, tubal or ectopic, miscarriage / termination.

- ☐ Yes
☐ No **Skip to Question 25.**
☐ Refuse to answer **Skip to Question 25.**

23. How many pregnancies in total have you had, including all live births, still births and tubal or ectopic pregnancies, miscarriages/terminations? Include current pregnancy if applicable.

_____ pregnancies

24. Are you currently pregnant?

- ☐ Yes
☐ No
☐ Unknown or refuse to answer

The next set of questions regards all of your pregnancies. Please include all pregnancies (live births, tubal or ectopic, stillbirths, and miscarriages/terminations), and all sons/daughters whether currently living or not. Please fill out the information for each pregnancy.

Repeat section for each pregnancy	Pregnancy #_____ (Please indicate pregnancy number)	
How old were you when you became pregnant?	_____ years <input type="checkbox"/> Don't recall/ refuse to answer	
What was the outcome of this pregnancy? <i>Circle one option</i>	<input type="checkbox"/> Full-term live birth <input type="checkbox"/> Preterm live birth <input type="checkbox"/> Stillbirth (>5 months) <input type="checkbox"/> Miscarriage(<5 months) <input type="checkbox"/> Induced/Elective abortion <input type="checkbox"/> Refuse to answer <i>Skip to next pregnancy if answer is stillbirth, Miscarriage, or a refusal.</i>	
Did you breastfeed this or any of these babies? <i>Select one option. If No, go on to the next question.</i> IF YES: How long did you breastfeed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't recall <input type="checkbox"/> Not applicable Number of: <input type="checkbox"/> Weeks _____ <input type="checkbox"/> Months _____	

	<input type="checkbox"/> Don't recall _____	
--	---	--

Breast Health History

25. Have you ever had a mammogram?

- ☐ Yes
- ☐ No **Skip to Question 27.**
- ☐ Unknown or refuse to answer **Skip to Question 27.**

26. When was your last mammogram?

____ / ____ / ____
MM DD YYYY

27. Have you ever had a breast biopsy?

- ☐ Yes
- ☐ No **Skip to Question 30.**
- ☐ Unknown or refuse to answer **Skip to Question 30.**

28. How many breast biopsies (positive or negative) have you had?

_____ biopsies

29. Have you ever had at least one breast biopsy with atypical hyperplasia?

- ☐ Yes
- ☐ No
- ☐ Unknown or refuse to answer

30. Have you ever been diagnosed with breast cancer?

- ☐ Yes
- ☐ No **Skip to Question 39.**
- ☐ Unknown or refuse to answer **Skip to Question 39.**

Breast Cancer Diagnosis *<to be completed only if Question 30 is "Yes">*

31. Approximate Date of Diagnosis: <dropdown> / <dropdown>
MM YYYY

32. What imaging technique was used to detect the breast mass? (Check all that apply)

- ☐ Mammogram
- ☐ Ultrasound
- ☐ MRI
- ☐ Other: _____

The following questions are regarding markers that are important in your breast cancer treatment.

33. ER (estrogen receptor) status:

- ☐ Positive
- ☐ Negative
- ☐ Unknown

34. PR (progesterone receptor) status:

- ☐ Positive
- ☐ Negative
- ☐ Unknown

35. HER2 (human epidermal growth factor receptor 2) status:

- ☐ Positive
- ☐ Negative
- ☐ Unknown

36. How was your breast cancer treated? (Check all that apply)

- ☐ Mastectomy
- ☐ Lumpectomy
- ☐ Radiation Therapy
- ☐ Chemotherapy
- ☐ Hormonal Therapy, such as tamoxifen or aromatase inhibitors (Arimidex/anastrozole, Aromasin/exemestane, Femara/letrozole)
- ☐ Targeted therapy, such as Herceptin/trastuzumab, Avastin/bevacizumab
- ☐ Other: _____
- ☐ Unknown

37. Approximate Height at Diagnosis: _____ feet _____ inches

38. Approximate Weight at Diagnosis: _____ pounds

Tobacco History

39. Have you smoked at least 100 cigarettes (5 packs) in your lifetime?

- ☐ Yes
- ☐ No, never **Skip to Question 42.**
- ☐ Unknown or refuse to answer **Skip to Question 42.**

40. Do you now smoke cigarettes?

- ☐ Not at all
- ☐ Some days
- ☐ Everyday

41. On average, how many packs do/did you smoke per day?

_____ packs

Alcohol History

The following questions are about your consumption of alcoholic drinks. These include beer, wine, wine coolers, and liquor (cocktails, whiskey, tequila, gin, rum, etc).

42. In your entire life, have you had at least a total of 12 drinks of any type of alcoholic beverage?

- ☐ Yes
- ☐ No **Skip to Question 45.**
- ☐ Unknown or refuse to answer **Skip to Question 45.**

43. Approximately how many drinks per week do you consume?

- ☐ 1-3
- ☐ More than 3
- ☐ Unknown or refuse to answer

44. How many years have you consumed alcohol?

_____ years

- ☐ Check box if you do not know or refuse to answer

Family History of Cancer

The next section is about the cancer history of members of your family. These include living and deceased family members. Please do not include half-siblings.

45. Are you adopted?

- ☐ Yes **Skip to Question 47**
☐ No
☐ Unknown or refuse to answer **Skip to Question 47**

46. Have any of your immediate blood relatives (parents, siblings, children) ever been diagnosed with cancer?

- ☐ Yes
☐ No **Skip to Question 47.**
☐ Unknown or refuse to answer **Skip to Question 47.**

For each of these family members, please tell us which of the above cancers they have/had and the approximate age of their diagnosis. Select “DK” if Don’t Know.

Family Member	Age Diagnosed	Type of Cancer
Drop Down	Number/DK	Drop Down

Birth Control

The next section is about the use of birth control pills and hormonal contraceptives. These are taken for various reasons, including preventing pregnancy, irregular periods, etc.

47. Have you ever taken birth control pills or other hormonal contraceptives for at least one month for any reason? These include pills, injections, implants, and patches.

- ☐ Yes, I am currently using (within 6 months)
☐ Yes, I used in the past (more than 6 months) ☐ No **Skip to Question 50.**
☐ Unknown **Skip to Question 50.**
☐ Refuse to answer **Skip to Question 50.**

48. How old were you when you started taking birth control pills/hormonal contraceptives?

- ☐ Less than 30
☐ 30-39
☐ 40-49
☐ 50-59
☐ 60 or older

49. What type of contraceptives did/do you use?

Type	Ever Taken?	Total number of years OR total number of months
Birth control pills	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	___ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Birth control injections (ex. Depo Provera)	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	___ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Birth control implants (ex. Norplant)	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	___ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Birth control patch (ex. Ortho Evra)	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	___ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Vaginal ring (ex. Nuva Ring)	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	___ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall

Hormone Replacement Therapy *(To be answered only if Question 19 is "Yes")*

The next section is about use of female hormones. These are often given to relieve menopausal symptoms such as hot flashes. These hormones may have been in the form of pills, shots, skin patches, creams, or vaginal suppositories.

50. Have you ever used hormone replacement therapy such as estrogen or progesterone? These include pills, shots, skin patches, creams, or vaginal suppositories. Do not include birth control pills or fertility drugs.

- ☐ Yes, currently use (within past 6 months)
☐ Yes, used in the past (longer than 6 months ago)
☐ No, never used **Skip to End.**
☐ Unknown **Skip to End.**
☐ Refuse to answer **Skip to End.**

51. In total, how long did you use replacement hormones? (years or months)

_____ years or _____ months

52. What type of hormone replacement therapy do/did you use? (Please complete table below)

Type	Ever taken?	Total number of years <u>OR</u> total number of months
Pills containing estrogen only (Ex. Premarin, Estrace, Estratest, Ogen)	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	____ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Pills containing progestin only (Ex. Provera, Cycrin, MPA)	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	____ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Pills containing estrogen plus progestin (Ex. Prempro, Premphase, Femhrt)	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	____ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Patches containing estrogen only	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	____ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Patches containing estrogen plus progestin (Ex: Combipatch)	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	____ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Type - Unrecalled	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	____ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall
Other: _____	<input type="checkbox"/> Currently <input type="checkbox"/> Formerly <input type="checkbox"/> No	____ <input type="checkbox"/> Years <input type="checkbox"/> Months <input type="checkbox"/> Don't recall

My Referrals

In order to reach as many female RPCVs as possible, we are asking that you provide the names and contact information for up to 3 female RPCVs who served between 1961 and 1990.

We will email or mail a letter to each woman you refer to the study with a link to the secure study website and an explanation of the study.

Please fill out as much information as you can on each RPCV so that we may invite them to participate in the study.

RPCV Referral #1

Full Name: _____
FIRST MIDDLE LAST

Email Address: _____

Telephone Number (including area code): _____

Served in Peace Corps <Country drop down> From <Year drop down> to <Year Drop down>

Sex: Male/Female

When we contact this RPCV, may we please tell her that you referred her to us?
Yes/no

BUTTON: SAVE

BUTTON: ADD PERSONAL NOTE

RPCV Referral #2

Full Name: _____
FIRST MIDDLE LAST

Email Address: _____

Telephone Number (including area code): _____

Served in Peace Corps <Country drop down> From <Year drop down> to <Year Drop down>

Sex: Male/Female

When we contact this RPCV, may we please tell her that you referred her to us?
Yes/no

BUTTON: SAVE

BUTTON: ADD PERSONAL NOTE

RPCV Referral #3

Full Name: _____

FIRST

MIDDLE

LAST

Email Address: _____

Telephone Number (including area code): _____

Served in Peace Corps <Country drop down> From <Year drop down> to <Year Drop down>

Sex: Male/Female

When we contact this RPCV, may we please tell her that you referred her to us?

Yes/no

BUTTON: SAVE

BUTTON: ADD PERSONAL NOTE

Study Description developed with NPCA

Peace Corps Connect home page sliding graphic headline:

Are you a woman who served in the Peace Corps between 1961 and 1990?

You could be a part of an exciting new study examining breast cancer risk.

(Graphic links to Study Info page)

Study Info Page

Breast Cancer Risk Study for Returned Peace Corps Volunteers

The National Peace Corps Association has partnered with researchers at Baylor College of Medicine to determine if there is a link between the risk of cancers, including breast cancer, and medications taken during Peace Corps service. The investigators have developed an online survey for RPCVs to measure health and health-affecting behaviors.

Our goal is that EVERY woman who served in the Peace Corps between 1961 and 1990 is represented in this study.

Studies in animals suggest that people who took a commonly used medication in the past to prevent or cure malaria may be at lower risk of developing some diseases today, such as cancer or heart disease. Baylor College of Medicine is developing studies to examine this link, beginning with this online survey to compare a large group of women who took the medication to a large group of women who didn't.

Female RPCVs who served between 1961 and 1990 represent an ideal group of people in whom to study this possible link, because about half of RPCVs took medication as part of their service and about half of them did not. Additionally, over 20 years has passed since their service and related medication use, so we can look at health changes over a long period of time.

The survey consists of about 50 questions and can be taken online or over the phone. Question topics include lifestyle risk factors for diseases and a brief medical history.

ACTION: Please share this page with people you served with in the Peace Corps.

PAGE 2 (JUMP LINKS TO THESE HEADERS)

How can I access the survey?

Identifying as many RPCVs who served between 1961 and 1990 as possible is critical to the study's validity; however, no exhaustive list of RPCVs who served during that time is available. To recruit a generalizable sample, the BCM researchers are using an innovative sampling method called Respondent-Driven Sampling. Based on social networks, this new approach works like a chain letter, in which participants answer the survey and invite their friends to answer the survey, adding onto the chain of RPCVs. The longer the chain of participants, the more representative the sample will be of the entire group of RPCVs. *You have to be referred to the study by another woman who served between 1961 and 1990 to take the survey.*

For more information on Respondent-Driven Sampling methodology, click here. [<Link to paper on RDS>](#)

This novel sampling method requires a small group of a few hundred RPCVs to start a movement that will grow to up to 18,000 RPCVs! Researchers have compiled a list of several hundred female RPCVs who will plant the seeds of the survey. Each of these women will invite up to 7 other RPCVs to participate. Those 7 women will each invite 7 more women, and so on.

ACTION: Watch your email for an invitation to fill out the survey and be sure to invite your friends to participate when you get one.

Who can take the survey?

We would like every woman who served between 1961 and 1990 to be represented in this study. No matter where you served, what medications you took or did not take, or if you have even been diagnosed with cancer or not, if you are a woman who served between 1961 and 1990, then you can take the survey.

To get a complete picture of all the women who served between 1961 and 1990, the researchers also need to count those who have died since their service. If you served with women who have died, you can give the researchers their names and service dates and they can be counted as well. To submit the name of a woman who has died, [click here](#).

What about men or those who didn't serve in the Peace Corps?

Although men will not fill out this RPCV survey, there will be studies in the future that include men. If you would like to learn about future studies, you can [join our mailing list](#).

Men or friends of the Peace Corps are encouraged to submit names of women who have died since their service. If you served with women who have died, you can give

the researchers their names and service dates and they can be counted as well. To submit the name of a woman who has died, [click here](#).

Why should I take this survey? Who benefits?

While there are no direct benefits to the RPCVs who help with the survey, this survey may help researchers discover new uses for an off-patent (which means that no pharmaceutical company owns it) and inexpensive drug.

Who is paying for this study?

In the early 1990s, a powerful grassroots advocacy movement campaigned for an increase in breast cancer research funding, and in 1993 the National Breast Cancer Coalition presented President Clinton with a 2.6-million signature petition for “a comprehensive plan to end the breast cancer epidemic.” Congress responded by appropriating funds targeted specifically toward winning what came to be known as “The War on Breast Cancer.” This appropriation marked the beginning of the Congressionally Directed Medical Research Program (CDMRP). The CDMRP is a unique partnership among the U.S. Congress, the public, and the Department of Defense to reduce bottlenecks and gaps in medical research. The project is funded by a grant from the Congressionally Directed Medical Research Projects administered by the US Department of Defense.

CDMRP is funded through the Department of Defense (DoD), via annual Congressional legislation known as the Defense Appropriations Act. For most programs, the DoD sends a multi-year budget request to Congress in the form of the President's Budget. However, dollars for the CDMRP are not considered part of the DoD's core mission, and are therefore not included in the DoD's requested budget. Rather, the dollars to fund CDMRP are added every year during the budget approval cycle by members of the House or Senate, in response to requests by advocates. This gives the CDMRP a unique ability to respond quickly to changes in science and public need. In addition to breast cancer, CDMRPs support research for diseases such as ALS (Lou Gehrig's disease), MS, and autism.

Are there any risks to participating in the study?

The risks to you are minimal. Participation in research may involve some loss of privacy. However, your records will be handled as confidentially as possible. Access will be limited to the data manager and the researchers organizing the study and will require a password. No information will be used for research without additional permission. Your contact information will not be shared with anyone outside of Baylor College of Medicine.

Are there any financial considerations?

There will be no cost or payment to RPCVs or their loved ones who respond to the survey.

How long will the study take?

The online survey will take a participant up to 40 minutes. You will be able to save the survey at any time to return and log into the study website to finish it later.

What about RPCVs who do not have Internet access?

The study can be completed over the telephone.

What is the National Peace Corps Association's role in this study?

The National Peace Corps Association is assisting Baylor College of Medicine in raising awareness about this path-breaking study. The National Peace Corps Association will not have access to individual survey answers, but will help share the overall study results in a variety of ways. Because of the unique nature of this research and the potential for such a great benefit to society, NPCA is sharing its entire database with Baylor College of Medicine and helping to spread the word so that everyone within the greater Peace Corps community, including friends and family members of Peace Corps Volunteers, are informed about the study and encouraged to participate. *(You may control your preferences for such data sharing opportunities by selecting "profile update" accessible at <https://secure.peacecorpsconnect.org/npcassa>.)*

When can I see the final results of this study?

The survey results will be published in academic journals, on PeaceCorpsConnect.org, and will be emailed to people registered to receive information on future studies **<link to future studies registration>**. Because of the tremendous task of collecting surveys from up to 18,000 RPCVs, final survey results will not be collected, analyzed, and published until mid-2014.

What do I do if I have questions, now or later?

Contact the study team directly at XXX@bcm.edu.

CorpsChronicles: An Application Leveraging Social Networks for Online Epidemiologic Survey Studies

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INTRODUCTION: Exposure to chloroquine, an off-patent anti-malarial drug with a 60-year history of use by millions, reduces the incidence of breast cancer in genetically programmed rats by 37%. To study whether such exposure may have a protective effect in humans requires a robust bioinformatics system. CorpsChronicles, is a secure, database-backed web application developed to manage large, socially-oriented epidemiologic studies. The first such study is of Returned Peace Corps Volunteers (RPCVs) who served from 1961-1990 in malaria-endemic areas who received chloroquine prophylactically. CorpsChronicles was used to collect information from RPCVs to determine if chloroquine exposure in this cohort associates with reduced breast cancer incidence compared with the general US population.

METHODS: CorpsChronicles is a Java Enterprise Edition 6 application that uses the model-view-controller architecture with the JBoss Seam framework to manage its various components. The application runs within JBoss 7 middleware and utilizes Oracle 11g for data persistence, though Hibernate makes it possible to swap out Oracle for other database management systems. Security is managed by enhanced Seam security, encrypted passwords, role-based permissions, Captchas, and unique “coupon” codes that serve as keys for respondents. Survey skip patterns are managed by Drools rules engine to allow independent, business-driven rules to be implemented for individual studies. “Friend recommendations” of respondents are based on a novel social network sampling methodology, Respondent-Driven Sampling (RDS), in which initial respondents (“seeds”) identify members of their social network who may want to participate and these members in turn identify members of their network thus creating network “chains” for each seed. Data from links in each chain are compared back to their seed data using RDSAT freeware; demographic and clinical characteristic data is compared between groups using chi square or Fisher’s exact test and t-test or Wilcoxon rank-sums. Multivariate logistic regression is used to assess associations between chloroquine exposure and breast cancer incidence, with the Network Scale-Up Method, a social networking method, applied to estimate the hard-to-count population of RPCVs.

RESULTS: CorpsChronicles (i) allows research subjects to securely answer dynamic questionnaires; (ii) manages electronic recruitment and referral workflows; (iii) sends email reminders to participants to complete surveys; and (iv) provides feedback to end users on the overall progress of the study in a way that does not compromise the results. Because breast cancer known risk factors include family history, race, and lifestyle, the online survey elicits self-reported data on potential confounding variables which will be accounted for in the statistical analysis to maximize internal validity. Two hundred highly-connected RPCVs were selected as initial seeds, with a goal of 17,000 respondents across all chains. Interim analyses were performed at one and two months post-activation to ensure appropriate accruals with RDS.

DISCUSSION: In this talk, sampling mechanisms, technical components of CorpsChronicles and preliminary results of the study will be discussed.

Designing a Translational Epidemiologic Study: Chloroquine and breast cancer chemoprevention in Returned Peace Corps Volunteers

Krystal Sexton, PhD¹ Amy M. Harris, MPH^{2,3} Kara McArthur^{2,3} Melissa L. Bondy, PhD¹ Susan Hilsenbeck, PhD¹ Lauren Becnel, PhD¹, Pamela Mayfield¹, Orla Conneely, PhD¹
Courtney M. Queen, PhD³ Margaret R. Spitz, MD¹ Clifford C. Dacso, MD, MPH^{1,2,3}

(1) Baylor College of Medicine, (2) The Methodist Hospital Research Institute, Abramson Center for the Future of Health, (3) University of Houston



INTRODUCTION

This study represents a multidisciplinary approach for drug repositioning through translational research using novel sampling & analysis methods.

Background

- Drug Repositioning is a promising approach to reducing the cost and timeline of new cancer drug development (routinely >\$1 billion and 10-15 years for FDA approval).
- Agents with established toxicologic, pharmacokinetic, and pharmacodynamic profiles are redeployed for new conditions.
- Following-up laboratory screening of such drugs with well-designed retrospective cohort studies, rather than a traditional, prospective clinical trial, could greatly expedite the identification and testing of promising drugs.

Chloroquine, an off-patent malaria prophylaxis with a 60-year history in millions of people, reduces the incidence of breast cancer in rats by 37%. [3-5]

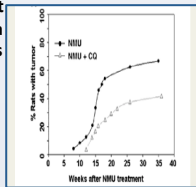


Fig. 1: Chloroquine reduces the incidence of NMU-induced mammary tumors in WT female Wistar-Furth rats (dark line), but shows no breast cancer protective effects in a BALB/c p53-null mammary epithelium model (light line). [5]

The challenge, particularly in the context of the dismal success rate of translational medicine [1], was to design an epidemiological study that **quickly and cost-effectively** determine chloroquine's effectiveness in humans.

Challenges in designing the study

- Time: Breast cancer can develop several decades after exposure to chloroquine.
 - A prospective study would require 10 - 50 years of follow up
- Study population: This study requires a representative sample of a well-defined study population
 - The study population must include participants with and without breast cancer, including those who have died of breast cancer.
- Risk factors: Breast cancer is a complex disease affected by family history of breast cancer, race, and lifestyle factors.

OBJECTIVE

Design an epidemiologic study to quickly, safely, and cost-effectively evaluate the effect of chloroquine on breast cancer risk in humans.

ACKNOWLEDGEMENTS

Apollo McOwity, Abramson Center for the Future of Health, Funded by the Department of Defense CDMRP program, National Peace Corps Association



METHODS

Study Design: A retrospective cohort study

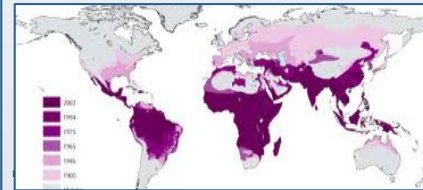
- Exposure of Interest:** Use of chloroquine as malaria prophylaxis before the year 1990.
- Timeline for exposure ends in the year 1990 because this is when the CDC revised its recommendations for malaria prophylaxis in resistant regions away from chloroquine.
 - Timeline also takes into account the long latency of breast cancer.
 - Chloroquine use measured by self-report and cross-referenced by Peace malaria prevention protocols by year and location.

Outcome: Breast cancer diagnosis (self-reported)

Population: Female Returned Peace Corps volunteers (RPCVs) who served between 1961 and 1990 (N=51,828). During that period, ~65% of volunteers were required to take chloroquine for the term of their service.



Fig. 2: Peace Corps countries



Respondent-Driven Sampling [2,7]

- RPCVs are a highly educated group of people who tend to have tight social relationships with other RPCVs.
- Large membership association (National Peace Corps Assoc) and 100s of small membership groups.
 - Respondent-Driven Sampling (RDS) is a variation of snowball sampling that builds a broad representative sample.
 - Uses a mathematical system for weighting the sample to compensate for its not having been drawn as a simple random sample.
 - Allows for valid inferences about the characteristics of the population from which the sample is drawn.
 - Starts with a sample of the target group (called "seeds") and expands through successive waves of recruitment, capitalizing on strong social ties among group members.
 - RDS has never been done using Internet-based data collection on this scale

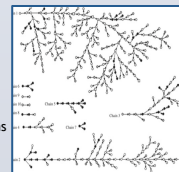


Fig. 4: RDS chains

New Referral Workflow

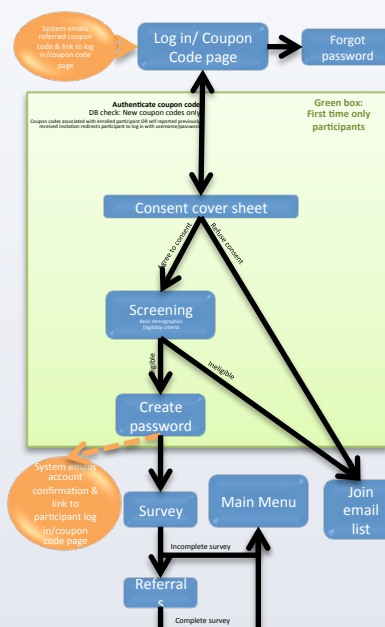


Fig. 5: New Referral Workflow

DATA COLLECTION

Online Data Collection Tool

Developing a proprietary data collection application, which will:

- Collect survey responses online with piping and skip patterns
- Allow participants to input referrals
- Track RDS chains of referrals
- Follow up with participants via email to increase response rate
- International and national standards compliance (CDISC BRIDG model, NCI EVS controlled vocabularies and data elements)
- Technology stack: Java Enterprise Edition 6, JBoss 7, RHEL 5, Oracle 11g, F5 proxy server

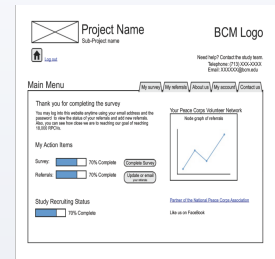
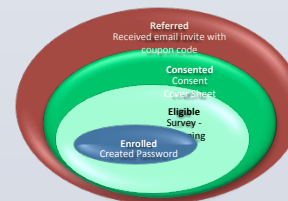


Fig. 7: Online Data Collection Tool Wireframe

DATA ANALYSIS

- The online RDS data will be analyzed using the Respondent Driven Sampling Analysis Tool (RDSAT) (Ithaca, NY).
- Demographic and clinical characteristics will be compared between groups.
- Categorical variables (e.g., family history) - chi square or Fisher's exact test
- Continuous variables (e.g., age at diagnosis) - t-tests or Wilcoxon rank-sum.
- RDSAT will calculate RDS weights.
- Multivariate logistic regression model will be used to assess the association between chloroquine exposure and breast cancer, adjusted for confounders.
- Breast cancer incidence and survival rates from SEER database and CDC.
- Sample size & minimum detectable ORs estimated using $\alpha=0.05$ and $\beta=0.20$ and various response rates

Assumption	Response Rate	Final Respondents	Expected Breast Cancer in Unexposed
1. 1 subject	50%	1704.5	1409.4
2. 2 subjects	40%	4262.3	3523.9
3. 3 subjects	30%	8524.6	7047.8
4. 4 subjects	20%	17049.1	14094.7
5. 5 subjects	10%	34098.2	28189.4

This is equivalent to changing "lifetime risk" from 1 in 9 to 1 in 12 with an associated number needed to treat of 36.

EXPECTED RESULTS

As in any retrospective study design, we must work to minimize bias and confounders. However, the gains in cost and time efficiencies allow the translation of preclinical data on breast cancer chemoprevention into the repositioning of a well-characterized and relatively benign drug to reduce breast cancer risk.

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C3PR, CODR & Corps Chronicles: Case Studies of Clinical and Epidemiological Research Databases within the DLDCC

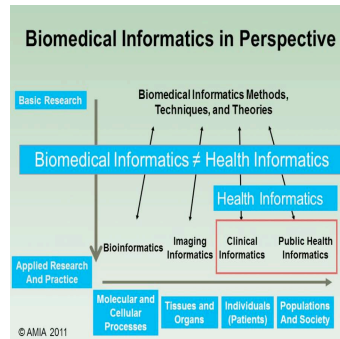
Pamela K. Mayfield, Apollo McOwiti, Jonathan Barney, Yolanda Darlington, Geetu Vanjani and Lauren B. Becnel

Biostatistics and Informatics Shared Resource (BISR), Dan L. Duncan Cancer Center & Lester and Sue Smith Breast Center, Baylor College of Medicine

Abstract

The Biomedical Informatics Group (BIG) of the DLDCC Biostatistics and Informatics Shared Resource provides services to Cancer Center members conducting clinical or epidemiologic research. BIG members were actively involved in establishing national and international data and object standards such as the NIH's standardized case report forms and components of the BRIDG model from the Clinical Data Interchange Standards Consortium (CDISC). Locally, we have implemented these standards in sister clinical research databases, C3PR and CODR. C3PR is a patient registration system created by the National Cancer Institute that BIG hosts to manage core study and patient data for all cancer clinical trials. Certain gaps in C3PR functionality (e.g. streamlined generation of Summary 4 and other reports, data management for PRMS and data review oversight committees) were addressed with the design/creation of a sophisticated, web-based companion application, CODR, which is tightly integrated with C3PR and provides an end-to-end view of clinical trial activity across all DLDCC programs. In addition to the standards-based clinical research support, BIG is currently implementing Corps Chronicles, a system that allows tens of thousands of research subjects to securely answer questionnaires using rules engine-managed set of logic. As a result, this web-based system must be highly scalable, able to handle thousands of simultaneous connections, and incorporate workflow and business logic to manage numerous recruitments, accruals and both internal and external communications (eg, reminders to participants to complete surveys). Although the initial system is being built in support of a breast cancer prevention study involving Peace Corps volunteers, the system design will be generalized to allow addition of survey-based studies for other cancers in the future.

Types of Informatics



BISR Contributions & Collaborations

LOCAL

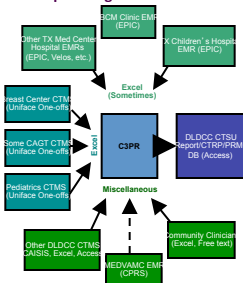
- Developed & hosted international and national standards-compliant online databases
- Clinical & epidemiological/population science research focus areas

NATIONAL & INTERNATIONAL

- Participated in the creation of standard case report forms for clinical trials
- Major co-developers of the NCI Life Science Business Analysis Model (BAM)
- Contributors to the Clinical Data Interchange Standards Consortium's (CDISC) BRIDG Domain Analysis Model & NCI Enterprise Vocabulary Services terminologies and data elements

C3PR: Participant Registration & Reporting

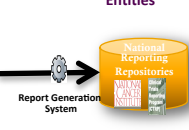
Sources of Participant Registration Data for the DLDCC



Study & Participant Registration Management in C3PR



Reporting to National Oversight Entities



Contributions to National Clinical Trials Management: Standard Case Report Forms

Form ID	Form Name	Form Description	Form Status
1	Form 1	Form 1 Description	Active
2	Form 2	Form 2 Description	Active
3	Form 3	Form 3 Description	Active
4	Form 4	Form 4 Description	Active
5	Form 5	Form 5 Description	Active

Acknowledgements

- CTSU Staff
- Sarah McNeese, PhD
- Martha Mims, MD PhD

CODR: Clinical Trials Oversight

FEATURES

- Secure, online database for clinical trials oversight committee (IRB, DSM, etc.) management
- Provides reminders of studies with upcoming & overdue reviews
- Fully integrated with C3PR

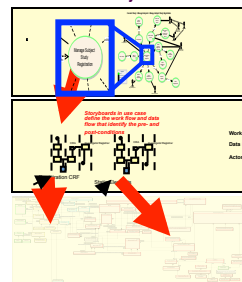
Oversight Committee Management & Reporting



CODR Data Model Using CDISC Standards



Contributions to National Clinical Trials Management: Data and Object Models



NCI Biomedical Research BAM UML Use Cases Are Used to Create BAM Activity Diagrams from which Components of the BRIDG Object Models Were Developed

Acknowledgements, See C3PR Section

Corps Chronicles: Large Epidemiological Studies

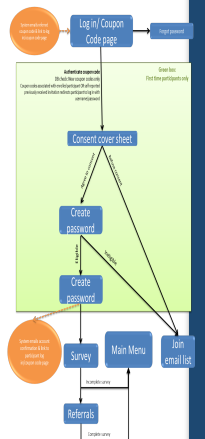
FEATURES

- Secure, online database for survey creation and collection & management of survey responses
- Utilizes cutting-edge statistical sampling methodology, RDS, and standard data elements and objects from NCI, CDISC, etc.
- "Social network" like features showing interpersonal network connectivity among participants
- First study investigating effects of chloroquine in breast cancer
- Useful for complex studies with thousands of participants where existing tools such as RedCap do not meet requirements

Survey and Referral Management



Study Participant Workflow



PARTICIPANTS

- Fill out online survey s with piping and skip patterns
- Input referrals
- Track RDS chains of referrals
- Receive follow up email reminders

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